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| 10/659,815 | 09/11/2003 | Percy Bennwik | 00843/2/US | 5254 |

7590
Pharmacia Corporation
Global Patent Department
P.O. Box 1027
St. Louis, MO 63006

01/11/2008

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| EXAMINER |
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WEATHERBY, ELLSWORTH

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| ART UNIT | PAPER NUMBER |
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3768

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01/11/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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| Office Action Summary | Application No. 10/659,815 | Applicant(s) BENNEWIK, PERCY | |
| | Examiner Ellsworth Weatherby | Art Unit 3768 | |

– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-36 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>6/28/2004</u> . | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-3, 6-11, 15, 30, 33, and 36 are rejected under 35 U.S.C. 102(b) as being anticipated by Vo (USPN 5,171,306).
3. Vo '306 (hereinafter Vo) teaches a method for sensing the state of an eye of a human subject, the method comprising measuring light reflected from an ocular surface and comparing the measured light to a reference (col. 8, l. 65- col. 9, l. 30). Vo further teaches sensing the state of the eye by the above method, and controlling whether a substance is delivered to the eye whereby the substance is so delivered only when the eye is sensed to be open (col. 2, ll. 55-60).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 4 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vo.

6. Vo teaches all the limitations of the claimed invention except for expressly teaching that the light source is a light emitting diode. However, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify Vo to include a LED. The motivation to modify Vo would have been to use any of a finite number of small light emitting means commonly available in the art at the time of the invention.

7. Claims 5, 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Vo in view of Weinblatt (USPN 4,659,197).

8. Vo teaches all the limitations of the claimed invention except for expressly teaching except for expressly teaching that the light measured is red or infrared light.

9. In a similar field of endeavor, Weinblatt '197 (hereinafter Weinblatt) teaches as well known in the art using infrared light to monitor the state of an eye (col. 1, ll. 11-24).

10. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Vo in view of Weinblatt. The motivation to modify Vo in view of Weinblatt would have been to monitor the eye without distracting the user.

11.

12. Claims 12-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vo in view of Rafal et al. (USPN 5,610,673).

13. Vo teaches all the limitations of the claimed invention except for expressly teaching that light reflected from the ocular surface is measured with a sampling frequency of at least about 20 Hz or 50 Hz or 100 Hz.

14. Rafal et al. '673 (hereinafter Rafal) teaches monitoring the position of the pupils at a rate of approximately 1000 Hz (col. 1, l. 48- col. 2, l. 2).

15. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Vo in view of Rafal. The motivation to modify Vo in view of Rafal would have been to permit observation of the measurement zone by the human eye without any perception of flicker.

16.

17. Claims 16-20, are rejected under 35 U.S.C. 103(a) as being unpatentable over Vo in view of Booth et al. (USPN 5,053,000).

18. Vo teaches all the limitations of the claimed invention except for expressly teaching the substance delivered is an ophthalmic drug selected from the group consisting of demulcents, antimycotics, antibacterials, antivirals, steroids, NSAIDs, selective cyclooxygenase-2 inhibitors, acetylcholine blocking agents, adrenergic agonists, beta-adrenergic blocking agents, carbonic anhydrase inhibitors, prostaglandins, antihypertensives, antihistamines, anticataract agents, and topical and regional anesthetics. Vo also does not expressly teach that the substance delivered is an ophthalmic drug selected from the group consisting of acebutolol, aceclidine, acetylsalicylic acid, N4 acetylsulfisoxazole, alclofenac, alprenolol, amfenac, amikacin, amiloride, aminocaproic acid, p-aminoclonidine, aminozolamide, anisindione, apafant,

atenolol, azithromycin, bacitracin, benoxaprofen, benoxinate, benzofenac, bepafant, betamethasone, betaxolol, bethanechol, brimonidine, bromfenac, bromhexine, bucloxic acid, bupivacaine, butibufen, carbachol, carprofen, cefixirne, cefoperazone, cefotaxime, cefiazidime, ceftizoxime, ceftriaxone, celecoxib, cephalexin, chloramphenicol, chlordiazepoxide, chlorprocaine, chlorpropamide, chlortetracycline, cicloprofen, cinmetacin, ciprofloxacin, clidanac, clindamycin, clonidine, clonixin, clopirac, cocaine, colistin, cromolyn, cyclopentolate, cyproheptadine, demecarium, dexamethasone, dibucaine, diclofenac, diflusinal, dipivefi-in, domeclocycline, dorzolamide, doxycycline, enoxacin, epinephrine, erythromycin, eserine, estradiol, ethacrynic acid, etidocaine, etodolac, etoricoxib, 1700843/2/US fenbufen, fenclofenac, fenclorac, fenoprofen, fentiazac, flufenamic acid, flufenisal, flunoxaprofen, fluorocinolone, fluorometholone, flurbiprofen and esters thereof, fluticasone propionate, furaprofen, furobufen, furofenac, furosemide, gancyclovir, gentamicin, gramicidin, hexylcaine, homatropine, hydrocortisone, ibufenac, ibuprofen and esters thereof, idoxuridine, indomethacin, indoprofen, interferons, isobutylmethylxanthine, isofluorophate, isoproterenol, isoxepac, ketoprofen, ketorolac, labetolol, lactorolac, latanoprost, levo-bunolol, lidocaine, lonazolac, loteprednol, mafenide, meclofenamate, medrysone, mefenamic acid, mepivacaine, metaproterenol, methacycline, methanamine, methylprednisolone, metiazinic, metoprolol, metronidazole, minocycline, minopafant, miroprofen, modipafant, nabumetome, nadolol, namoxyrate, naphazoline, naproxen and esters thereof, neomycin, nepafenac, nitroglycerin, norepinephrine, norfloxacin, nupafant, ofloxacin, olopatadine, oxaprozin, oxepinac, oxyphenbutazone, oxyprenolol, oxytetracycline,

parecoxib, penicillins, perfloxacin, phenacetin, phenazopyridine, pheniramine, phenylbutazone, phenylephrine, phenylpropanolamine, phospholine, pilocarpine, pindolol, pirazolac, piroxicam, pirofen, polymyxin, polymyxin B, prednisolone, prilocaine, probenecid, procaine, proparacaine, protizinc acid, pyrimethamine, rimexolone, rofecoxib, salbutamol, scopolamine, silver sulfadiazine, sotalol, sulfacetamide, sulfanilic acid, sulfisoxazole, sulindac, suprofen, tenoxicam, terbutaline, tetracaine, tetracycline, theophyllamine, timolol, tobramycin, tolmetin, travoprost, triamcinolone, trimethoprim, trospectomycin, unoprostone, valdecoxib, vancomycin, vidarabine, vitamin A, warfarin, zomepirac and pharmaceutically acceptable salts, esters and prodrugs thereof.

19. Booth et al. '000 (hereinafter Booth) teaches delivering drugs selected from the group listed above (col. 2, ll. 20-45).

20. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Vo in view of Booth. The motivation to modify Vo in view of Booth would have been to provide the medication required by the patient as is the purpose of the invention of Vo.

21.

22. Claims 22-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vo in view of Booth as applied to claim 21 above, and further in view of Embleton et al. (USPN 6,425,888).

23. Vo in view of Booth teaches all the limitations of the claimed invention except for expressly teaching that the carbonic anhydrase inhibitor is dorzolamide or a salt thereof.

Vo in view of Booth also does not expressly teach delivering a prostaglandin.

24. Embleton et al. '888 (hereinafter Embleton) teaches delivering dorzolamide and/or a prostaglandin (col. 12, ll. 9-67).

25. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Vo in view of Booth with Embleton. The motivation to modify Vo in view of Booth with Embleton would have been to provide the medication required by the patient as is the purpose of the invention of Vo.

26. Claims 25-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vo in view of Booth or Vo in view of Booth and Embleton.

27. Vo in view of Booth or Vo in view of Booth and further in view of Embleton teach delivering medications to a patient's eye. The object of Vo's invention is to efficiently deliver a medication. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify Vo in view of Booth or Vo in view of Booth and Embleton to include any known medication for treatment of a particular disease or ailment of the eye. The motivation to modify Vo in view of Booth or Vo in view of Booth and further in view of Embleton would have been to safely and efficiently provide a patient with the medication prescribed by their doctor.

28. Claims 31-32 and 34-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vo in view of Cornish (USPN 6,033,389).

29. Vo teaches all the limitations of the claimed invention except for expressly teaching a standoff to position and orient the sensor at a consistent distance from and angle to the eye wherein the standoff comprises an eye-cup having a distal rim adapted to contact a surface of the subject's face around the eye.

30. In the same field of endeavor, Cornish '389 (hereinafter Cornish) teaches a medicament dispensing device that has a cup that appropriately positions and orients the dispenser (Figure 1).

31. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Vo in view of Cornish. The motivation to modify Vo in view of Cornish would have been to improve the precision of the system by standardizing the distance to the eye using the cup taught by Cornish.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ellsworth Weatherby whose telephone number is (571) 272-2248. The examiner can normally be reached on M-F 8:30 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eleni Mantis-Mercader can be reached on (571) 272-4740. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

EW

A handwritten signature in black ink, appearing to read "Bill", is located in the lower right quadrant of the page.